BEFORE THE ARIZONA MEDICAL BOARD

In the Matter of **KERWIN J. LEBEIS, M.D.** Holder of License No. **16331** For the Practice of Allopathic Medicine In the State of Arizona.	Board Case No. MD-02-0424A **FINDINGS OF FACT, CONCLUSIONS OF LAW AND ORDER** (Letter of Reprimand)

The Arizona Medical Board ("Board") considered this matter at its public meeting on October 9, 2003. Kerwin J. Lebeis, M.D. ("Respondent") appeared before the Board without legal counsel for a formal interview pursuant to the authority vested in the Board by A.R.S. § 32-1451(H). During the interview Respondent agreed to undergo evaluation at the Physician Assessment and Clinical Education Program ("PACE") and to enter an Interim Consent Agreement for a Practice Restriction providing that he not practice psychiatry or prescribe pharmacological agents until further order of the Board. The Board continued the interview until the results of the PACE evaluation were received.

The Board concluded this matter at its August 12, 2004 public meeting. Respondent again appeared without legal counsel. The Board voted to issue the following findings of fact, conclusions of law and order after due consideration of the facts and law applicable to this matter. The Board also voted to require Respondent to attend additional clinical training recommended by the PACE evaluation and that the Interim Consent Agreement for Practice Restriction remain in effect until Board Staff received proof of that Respondent successfully completed the training. Such proof was received on October 4, 2004 and the Interim Practice Restriction was removed on October 6, 2004.

FINDINGS OF FACT

1. The Board is the duly constituted authority for the regulation and control of the practice of allopathic medicine in the State of Arizona.

2. Respondent is the holder of License No. 16331 for the practice of allopathic medicine in the State of Arizona.

3. The Board initiated case number MD-02-0424A after being informed that the Arizona Department of Corrections ("ADOC") had placed Respondent on administrative leave after Respondent used atypical antipsychotic medications and performed unauthorized experiments on nineteen inmates without informed consent. The experiments involved changing the dosages and medication regimens of nineteen patients.

4. Respondent testified that he had respect for the rules and boundaries of the medical profession and that his intention was always to help patients. Respondent referred to an article he had provided to the Board regarding the intermittent dosing of atypical antipsychotic medications. Respondent noted that the article states that there is no scientific basis for continuous dosing of atypical antipsychotic medications. Respondent noted that approximately fifty years ago, when antipsychotic medications were first used, there was a treatment block model in electroconvulsive therapy for intermittent treatment. Also, while this applies to all psychiatric medications it is particularly important for atypical antipsychotic medications because of concern for side effects that are greater with continuous dosing, as well as the gap between efficacy and effectiveness. Respondent noted that there is still a problem, as the article points out, with the quality of life for psychotic schizophrenics and also for the level of functioning despite all treatment efforts.

5. Respondent also stated that the use of intermittent dosing by psychiatrists has been effective and could be more so with greater understanding. Respondent noted that he believes medicine is subject to fashion and that continuous medication is one of those things. Respondent also stated that continuous medication raises safety issues and does not address the gap between the efficacy, in terms of reducing symptoms, and the effectiveness of quality of life and functioning. Respondent noted he has tried to help patients in that manner.

6. Respondent was asked to describe his medical background and training and his current practice situation. Respondent stated that he went to Loyola University Medical School and then continued his residency and did some faculty work there. Respondent noted that he was Board Certified in Psychiatry in 1979 and moved to Phoenix in 1986. Respondent stated he was originally in private practice and then worked for ADOC for six years and for the last year and one-half he has not been practicing medicine.

7. Respondent was asked if any of the patients were harmed when he stopped their medications. Respondent stated that after a couple of weeks all nineteen patients were on a higher functioning level and he would say that they were not harmed. Respondent was asked how he decided which patients were better or worse when most patients were only in the unit for about two weeks. Respondent testified that he had been in the system for six years and that he had known some of the patients for years. Respondent was asked if he did any follow-up. Respondent testified that it was a brief intensive look over a couple of week period and then, after that, the diagnoses were looked into individually to sort out what kind of treatment should be continued. Respondent noted that there were a number of different psychotic diagnoses and some patients were not psychotic at the end of the study and they were treated accordingly.

8. Respondent was asked if he had authorization from the prisoners that he treated or from ADOC to perform his study. Respondent testified that he did not. Respondent testified that he believed the patients could be harmed by the medication they were taking so he did not consider getting consent for stopping medication he thought was harming the patient. Respondent testified that he talked over with every patient about how the medication was affecting their functioning, their quality of life, that the medication was causing worsening symptoms, and that he was attempting to lessen that.

9. The Board noted that ADOC apparently had an increase in precautionary watches because of concern when patients' medication was stopped. Respondent testified that he was not sure he knew about that. Respondent testified that he did not mean to be evasive, but that a lot of patients were on watches and a slight increase or decrease would be hard for him to keep track of. Respondent was asked if he had any study results that he would present to a reputable medical meeting. Respondent testified that it was not really a formally thought out study and that he observed some rather dramatic improvements in some patients and became concerned about what was happening in other patients.

10. Respondent was asked how ADOC became aware of the "project" Respondent was conducting. Respondent testified that he was very open about it and discussed it with everyone, including pharmacists, other psychiatrists, nurses, psychologists, and outside people. Respondent was asked what the opinions of those persons he discussed this with were regarding what he was doing. Respondent testified that the opinions varied and that some disagreed with what he was doing or he would not be before the Board. Respondent was asked if anyone he discussed this with suggested that he needed informed consent from the patients to experiment upon them.

Respondent stated that one of the psychologists brought it up and they discussed it. Respondent testified that his feeling at the time was that, since he was withdrawing a harmful substance from patients, it was not something that would ordinarily constitute the use of a consent form. Respondent stated that, for instance, if you have a patient who has a side effect from a medication, you do not usually need a separate consent form to stop the medication you think might be causing the side effect.

11. Respondent was asked that if his study was not formal, and he was not going to present or publish it, what he intended to do with the results. Was it meant to be anecdotal. Respondent testified that it was somewhat anecdotal. Respondent noted that he saw a symptom that was somewhat baffling and troublesome – these activating, aggravating, agitating symptoms of the atypical antipsychotic medication – and he thought it would be interesting to know how long it took for the side effect to go away. Respondent stated the study had a practical benefit to him at the time because he needed to know when he could breathe a sigh of relief that a patient was not going to be agitated by the medication and he could also look at the diagnosis more clearly without having trying to second-guess whether this was a side effect or a legitimate symptom of an illness.

12. Respondent was asked to define what he considered to be atypical antipsychotic medication. Respondent testified that in the 1950s the antipsychotic medication started out with Chlorpromazine and really was no different in terms of efficacy for any antipsychotic medication up until Clozaril or Clozapine. Respondent noted that was not used all that much in this State because of the fatal side effects. Respondent stated that extensions of Clozaril became the atypical antipsychotic medications that are supposed to combat some of the sluggishness that the old antipsychotic medications caused and have reduced side effects. Respondent noted that

they then turned out to have different side effects. Respondent was asked if other psychiatrists use the term "atypical antipsychotic medication." Respondent stated that this was standard terminology and that a lot of psychiatrists consider them a first-line treatment.

13. Respondent was asked if most psychiatrists would not discontinue these medications as he did. Respondent stated that psychiatrists regularly discontinue them when a patient's behavior gets out of control. Respondent was asked what psychiatrists use instead. Respondent stated that different psychiatrists use different ploys, some use polypharmacy. Respondent was asked if it would be a fair statement that maybe the patients might not be able to understand the rationale for their drugs, for changing them. Respondent testified that technically the patients are considered competent, but you could argue that all of the consent forms used for schizophrenics could be called into question. Respondent noted that the patients are fairly rational when you speak to them, but sometimes do not cooperate if they are out of it.

14. Respondent testified that taking the patients off of the medications for given periods of time, or reducing the medication, was an attempt to get rid of the side effects and see how much improvement would come out of it. Respondent noted that some patients seem to respond and improve, at least in the short term. Respondent was asked if he had any specific written treatment plan for the individual patients that he could document. Respondent testified that part of the problem in psychiatry is that there are not diagnoses like diabetes or hypertension that stay the same. Respondent stated that a psychiatrist may think someone is schizophrenic and when they are taken off medication there may be a different diagnosis – bipolar for instance – that needs to be addressed at that time.

15. It is unprofessional conduct for a physician to use experimental forms of diagnosis and treatment without adequate informed patient consent, and without conforming to generally accepted experimental criteria, including protocols, detailed records, periodic analysis of results and periodic review by a medical peer review committee as approved by the federal food and drug administration. A.R.S. § 32-1401(27[1])(y).

16. The standard of care required Respondent to appropriately conduct a research project, to not manipulate medications contrary to manufacturer recommendations, to obtain informed consent, and to follow proper protocols.

17. Respondent fell below the standard of care because he inappropriately conducted a research project in which he manipulated medications contrary to manufacturer recommendations without informed patient consent and without following proper protocols.

18. Some of the patients involved in Respondent's research project were harmed because there was an increase in psychiatric symptoms resulting in increased precautionary watches.

19. The Board noted that Respondent had been extremely cooperative with the Board and complied with everything the Board required he do throughout this investigation. The Board also noted that Respondent scored very high on the PACE examinations and had some of the highest scores on the National Board of Medical Examiners Standardized Tests ever recorded by a PACE participant. The Board also recognized that Respondent had completed courses in practice guidelines for various types of psychiatric treatment as well as other courses.

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[1] Formerly A.R.S. § 32-1401(26). Renumbered effective August 25, 2004.

CONCLUSIONS OF LAW

1. The Arizona Medical Board possesses jurisdiction over the subject matter hereof and over Respondent.

2. The Board has received substantial evidence supporting the Findings of Fact described above and said findings constitute unprofessional conduct or other grounds for the Board to take disciplinary action.

3. The conduct and circumstances described above constitute unprofessional conduct pursuant to A.R.S. § 32-1401(27)(y) ("[t]he use of experimental forms of diagnosis and treatment without adequate informed patient consent, and without conforming to generally accepted experimental criteria, including protocols, detailed records, periodic analysis of results and periodic review by a medical peer review by a medical peer review committee as approved by the federal food and drug administration or its successor agency."

4. The conduct and circumstances described above constitute unprofessional conduct pursuant to A.R.S. § 32-1401(27[2])(q) ("[a]ny conduct or practice that is or might be harmful or dangerous to the patient or the public.")

ORDER

Based upon the foregoing Findings of Fact and Conclusions of Law,

IT IS HEREBY ORDERED that Respondent is issued a Letter of Reprimand for performing experimental protocols on patients without informed consent.

RIGHT TO PETITION FOR REHEARING OR REVIEW

Respondent is hereby notified that he has the right to petition for a rehearing or review. The petition for rehearing or review must be filed with the Board within thirty (30)

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[2] Formerly A.R.S. § 32-1401(26). Renumbered effective August 25, 2004.

days after service of this Order. A.R.S. § 41-1092.09. The petition must set forth legally sufficient reasons for granting a rehearing or review. A.A.C. R4-16-102. Service of this order is effective five (5) days after date of mailing. If a motion for rehearing or review is not filed, the Board's Order is effective thirty-five (35) days after it is mailed to Respondent.

Respondent is further notified that the filing of a motion for rehearing or review is required to preserve any rights of appeal to the Superior Court.

DATED this 10th day of November, 2004.

THE ARIZONA MEDICAL BOARD

By _____
BARRY A. CASSIDY, Ph.D., PA-C
Executive Director

ORIGINAL of the foregoing filed this 12th day of November, 2004 with:

Arizona Medical Board
9545 East Doubletree Ranch Road
Scottsdale, Arizona 85258

Executed copy of the foregoing mailed by U.S. Certified Mail this 12th day of November, 2004, to:

Kerwin J. Lebeis, M.D.
Address of Record

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